FEB 16 2007

K070088

5 510(k) Summary

Submitter:	Thomas Y.S. Shen
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Date Prepared:	January 8, 2007
Trade Name:	Assure 4 Blood Glucose Monitoring System
Classification:	Glucose test system, 21 CFR 862.1345, Class II
Product Codes:	CGA
Predicate Device:	Glucosure BGM
Device Description:	Assure 4 consists of a meter, test strips, and control solutions for use in measuring blood glucose as an aid to monitor the effectiveness of diabetes control
Intended Use:	The Assure 4 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.
Functional and Safety Testing:	Clinical testing was done with persons with diabetes in addition to in-house testing for precision, interferences, linearity, altitude effects, hematocrit effects, minimum sample volume, stability, control solution functionality, and temperature and humidity effects.
Conclusion:	The modification to the original device does not adversely affect performance and the modified device is substantially equivalent to the unmodified predicate device.

9 Modified Device Information

NOTE:

- We refer to the modified device as the "Assure 4" or the "Modified Assure 4".
- We refer to the unmodified device as "Assure 3" or the "Unmodified Assure 3".

9.1 Description of Modified Device

Appendix 1 shows engineering diagrams of the Modified Assure 4 meter, code chip and test strip.

The Assure 4 measures electrical current generated by the interaction of glucose with glucose oxidase in its biosensor test strip. It uses a code chip for strip lot calibration.

Among the changes that have been made (described in Section 9.2), the code chip and test strip have been modified in shape and size to prevent Assure 4 and Assure 3 code chips and test strips from being used interchangeably.

9.2 Comparison to Unmodified Device

Table 1 (page 22) summarizes the similarities and differences between the Modified Assure 4 and the Unmodified Assure 3.

9.2.1 Similarities

The Modified Assure 4 device has the following similarities to the Unmodified Assure 3:

- Identical intended use statements
- Identical operating principle
- Identical fundamental chemistry
- Identical control solutions
- Identical base software and algorithm
- Identical meter LCD

9.2.2 Modifications

1. Modifications of Code Chip

    a. The Assure 4 code chip and meter code chip port were changed to prevent interchangeability with the Unmodified Assure 3 meter. The Assure 4 code chip physically cannot fit into the Assure 3 meter code chip port. The Assure 3 code chip is too short to make electrical contact, if inserted into the Assure 4 meter code chip port. (See Table 1, page 22, item 14).

2. Modifications of Test Strip

    a. The drop volume of the active chemistry was reduced from 5 µL to 2 µL.

    b. The concentration of glucose oxidase was increased to compensate for the decrease in absolute volume of active chemistry. This ensures that a sufficient electrical signal is generated and that glucose oxidase is not a rate-limiting step for high glucose levels. The resultant electrical signal can be accommodated with the existing algorithm and calibration procedures. Minor changes were also made in the concentration of the enzyme protector and non-reactive ingredients. (See Table 1, page 22, item 15 and Table 2, page 24).

    c. A mesh was eliminated from the Unmodified Assure 3 test strip. Elimination of the mesh allows the reduction in drop volume of the active chemistry, as the mesh absorbs and disperses the active chemistry; thereby increasing the size of the drop of active chemistry needed.

    d. A PET (polyethylene terephthalate) laminate film was added above the active chemistry "well" to create a capillary fill channel that directs the blood to the active chemistry site. Because the channel takes a small amount of blood to fill and because of the increased concentration of glucose oxidase, the test strip is now accurate to a minimum sample volume of 1.5 µL, instead of 3.0 µL. The design requires filling the Modified Assure 4 test strip from the side. (See Table 1, page 22, items 16 and 17).

    The Unmodified Assure 3 test strip also had the active chemistry site oriented so that it faced the side of the test strip (rather than being on the end of the test strip). The Unmodified Assure 3 test strip can be filled from the top or the side; whereas, the Modified Assure 4 test strip can be filled only from the side by touching the opening of the capillary channel.

    e. Strip length was reduced from 48 mm to 38 mm, reducing raw material costs. (See Table 1, page 22, item 18).

    f. To eliminate interchangeability of Assure 4 and Assure 3 test strips and meters, the Assure 4 meter has a "post" in the test strip holder which prevents insertion of the Assure 3 test strip. The Assure 4 test strip has a slot that allows insertion into the Assure 4 meter, bypassing the test strip holder "post". The Assure 4 test strip does not work in the Assure 3 meter because the slot in the Assure 4 test strip prevents the strip from pressing the switch wire in

the Assure 3 test strip holder. Therefore, insertion of the Assure 4 strip into the Assure 3 meter does not turn on the Assure 3 meter. The switch wire in the Assure 4 meter strip holder is off to one side, such that the slotted Assure 4 strip is able to turn on the Assure 4 meter. (See Table 1, page 22, item 19).

3. Modifications of Meter

   a. The code chip port for the Modified Assure 4 was changed to match the altered shape of the Assure 4 code chip. The Assure 4 code chip physically cannot fit into the Assure 3 meter. The Assure 3 code chip is too short to make electrical contact, if inserted into the Assure 4 meter code chip port. (See Table 1, page 22, item 14).

   b. The Modified Assure 4 meter test strip holder has a "post" to prevent usage of Unmodified Assure 3 test strips in the Modified Assure 4 meter. (See Table 1, page 22, item 19).

   c. The outer case of the Assure 4 meter was changed to:

      i. Improve aesthetics (curved shape on sides as opposed to straight sides of Unmodified Assure 3). (See Table 1, page 22, item 20).

      ii. Differentiate Assure 4 from Assure 3 for commercial reasons.

      iii. Accommodate the two AAA batteries used in the Modified Assure 4. The Assure 4 has a larger battery compartment and a new battery compartment door design. The Unmodified Assure 3 uses the smaller CR-2032 wafer battery. (See Table 1, page 22, item 29).

   d. The single meter button used to operate the meter has been made oval (instead of circular) for improved aesthetics. (See Table 1, page 22, item 21).

   e. Assure 4 units of measurement are mg/dL only and cannot be changed to mmol/L. (See Table 1, page 22, item 22).

   f. Assure 4 meter display shows numbers (9, 8, 7, etc.) for count down after blood application, instead of dashes (- - -, - -, -) used by the Assure 3. This change was made for aesthetic and commercial reasons. (See Table 1, page 22, item 23).

   g. Increased memory capacity to 50 results (up from 10) and added sequential number to all memory results. (See Table 1, page 22, item 24).

   h. New system for conducting control solution testing and resistive checking.

      i. In the Assure 3 meter, the user must sequentially insert both ends of a Check Strip into the test strip holder. This checks the meter function by applying a known resistive value to the meter. It also activates the Control Solution Mode for the meter. In the control solution mode, the Assure 3 meter uses the control solution calibration curves and does not store the control solution result in memory. (See Table 1, page 22, item 25).

ii. In the Modified Assure 4 meter:

1. an internal resistance has been added to the circuitry and this is checked upon start up of the meter, eliminating the need for the Check Strip. (See Table 1, page 22, item 25).
2. The user enters the control mode by inserting a test strip and pressing the single meter button once for Level 1 Control Solution, twice for Level 2 Control Solution. (See Table 1, page 22, item 26).
3. Control solution results are stored in memory and are marked with "c". (See Table 1, page 22, item 27).

i. Meter allows operation in a wider operating temperature range of 57°F – 104°F. The Unmodified Assure 3 operating range is 65°F – 100°F. For commercial reasons, we tested the Modified Assure 4 further and found that the system supports the wider 57°F – 104°F Operating Temperature range – there is sufficient temperature compensation in the algorithm to support this wider range. Both the Assure 4 and Assure 3 give out an error message (flashing temperature icon) when the meter is used outside its thermal operating range. (See Table 1, page 22, item 28).

j. Changed power supply from one CR-2032 battery to two AAA batteries, increasing the number of tests that can be run from 1000 to 3000 test per each set of batteries. (See Table 1, page 22, items 29 and 30).

k. Assure 4 dimensions and weight are slightly different from that of the Assure 3 meter. (See Table 1, page 22, item 31).

Table 1 (page 22) summarizes the similarities and differences between the Modified Assure 4 and the Unmodified Assure 3.

Table 1: Substantial Equivalence Table

#	Characteristic	Assure 4	Assure 3
1	Manufacturer	Apex	Identical
2	Methodology	Biosensor	Identical
3	Reference	Plasma	Identical
4	Blood Sample Type	Fresh capillary whole blood	Identical
5	Lot Calibration	Code Chip	Identical
6	Test Time (seconds)	10	Identical
7	Test Range (mg/dL)	30-550	Identical
8	On/Off w/ strip insertion	Yes	Identical
9	Auto Shut Off	Yes	Identical
10	Hematocrit Range	30-55%	Identical
11	Humidity Range	<85%	Identical
12	Altitude	7,000 ft	Identical
13	# of Meter Buttons	1	Identical
14	Code Chip Configuration	Code chip too large to work with Assure 3	Code chip too short to work with Assure 4
15	Concentration of Strip Ingredients per cm^2	See Table 2, page 24	See Table 2, page 24
16	Minimum Sample Vol.	1.5 µL	3 µL
17	Strip Fill	Capillary side fill	Non-capillary, top or side fill
18	Strip Length	38 mm	48 mm
19	Configuration of Strip and Meter Strip Holder	Strip slot and meter strip holder "post" to prevent usage with Assure 3	No slot in strip, thereby preventing usage with Assure 4
20	Configuration of Meter Case	Changes from Assure 3 for aesthetic reasons and to accommodate AAA batteries	Original Assure 3 aesthetics and battery compartment
21	Meter Button Shape	Oval	Round
22	Units of Measurement	mg/dL only	mg/dL or mmol/L
23	Count Down Method	Numbers (9, 8, 7...)	Dashes (---, --, -)
24	Memory Capacity	50 results, with sequential numbering	10 results, with no sequential numbering
25	Meter Resistive Check	Automatic resistive check occurs at meter turn on, using internal resistors	Insert Check Strip with 2 known resistive values during control solution testing process
26	Control Solution Mode	Insert strip; press button once for Level 1, twice for L 2; use control solution	Insert both ends of Check Strip, insert test strip, use control solution
27	Memory for Control Solution Results	Control solution tests stored and marked with "c"	Control solution results not stored in memory
28	Operating T° Range	57-104°F	64-100°F
29	Battery Supply, Battery compartment	Two AAA batteries and compartment to match	One CR2032 and compartment to match
30	Tests/Battery Set	3,000	1,000
31	Size/Weight	3.9" x 2.3" x 1.0"/2.5 oz.	3.9" x 2.3" x 0.8"/ 2.2 oz.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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FEB 16 2007

Re: k070088
Trade/Device Name: Assure 4 Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system.
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: February 6, 2007
Received: February 12, 2007

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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Enclosure

Indications for Use Statement

510(k) Number (if known): K070058

Device Name: Assure 4 Blood Glucose Monitoring System

Indications For Use:

Assure 4 Blood Glucose Meter:

The Assure 4 Blood Glucose Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertip. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Prescription Use _______ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Diagnostic Device

K070088